DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date: March 1, 2011

From: Timothy C. Grome, CSO

Subject: FDA 483 Response

To: Ruark Lanham, SCSO

Firm: Conceptus, Inc.
331 Evelyn Ave.
Mountain View, CA 94041

FEI: 1000221357

I reviewed the letter from the above referenced firm dated, 1/20/2011. I find no objection to the firm's response to Observation #1. The firm is not required to report injuries that occur as the result of the use of another manufacturer's device during the procedure to place their device if the injury occurs without their product being inserted in the hysteroscope, or unless the specific type of device was required in the instructions for use.

In the firm's response to Observation #2 they confirm that their (b) (4) being (b) (4) (b) (4) is a (b) (4) The firm states that (b) (4) being (b) (4) (b) (4) does not rise to the level of a serious injury. The firm stated that they do report such cases when surgical intervention is required. They denied that the (b) (4) being (b) (4) (b) (4) is not "likely" to lead to surgical intervention because in their (b) (4) (b) (4) No documentation was submitted in the response letter to illustrate this figure. Even though the cases with surgical removal are reported,

Endorsement Date: 4-7-2011

Responses to Observations #1, and #4 are adequate. Observations #2 and #3 will be covered in follow-up inspection within 4 months.

Ruark Lanham, SCSO
San Francisco District

Original: SAN-DO
cc: SJ-RP

MEMO
Date: March 1, 2011
To: Ruark Lanham, SCSO
From: Timothy C. Grome, CSO
FEI: 1000221357

according to the admitted practice (b) (4)
(b) (4)

The firm's response to Observation #3 was to revise the (b) (4)
The new (b) (4)
(b) (4) he Observation was that the (b) (4)
(b) (4) The potential effects of that failure mode could be determined from (b) (4)
(b) (4)

For Observation #4 was that the firm had not opened a CAPA specific to the (b) (4)
(b) (4)
(b) (4) When the firm the observation was corrected and verified.

Timothy C. Grome, CSO
San Francisco District

Att. 1 FDA 483 Response from Conceptus, Inc., Jan. 20, 2011 and supporting documents (63 pages)